

Application No. 09/685,297
Paper Dated June 26, 2003
Reply to USPTO Correspondence of March 5, 2003
Attorney Docket No. 3487-001146

REMARKS

In view of the applicant's Appeal Brief, the Patent Office has withdrawn its rejections based upon the prior art. The Patent Office has now rejected claims 1-9 under 35 U.S.C. § 112, first paragraph, "as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention."

Reconsideration is respectfully requested.

The examiner has raised a number of specific questions concerning the applicant's disclosure which will be dealt with one by one.

The examiner notes the absence of a "specific working example". As explained in MPEP § 2164.02: "Compliance with the enablement requirement of 35 U.S.C. 112, first paragraph, does not turn on whether an example is disclosed." As explained in the next paragraph of the MPEP: "The specification need not contain an example if the invention is otherwise disclosed in such manner that one skilled in the art will be able to practice it without an undue amount of experimentation. *In re Borkowski*, 422 F.2d 904, 908, 164 USPQ 642, 645 (CCPA 1970)." As will become apparent by the applicant's response to the examiner's specific questions, those skilled in the art would have no difficulty practicing the applicant's invention without undue experimentation.

The examiner states: "There are no specifics given as to how the N specimens are 'prepared'".

Mass spectrometry, for example, is a well-established art. The same is true of other instruments that analyze fluid specimens. Samples (specimens) are prepared by well-

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known methods available to those of ordinary skill in the art. For example, samples are diluted in a solvent that is suitable for the method of introduction to be used and diluted samples are placed in vials or other sample containers for analysis. The samples are then ready for introduction, which may be directly or via a gas or liquid chromatograph. The use of a chromatograph to introduce samples to mass spectrometers is well known as shown in Norman U.S. Patent No. 5,508,204 previously cited by the examiner. There is nothing special or unusual about the preparation of fluid samples for the practice of applicant's invention.

The examiner states: "Furthermore, there is no reasoning given for 'introducing a first combination of r specimens where r is less than N into a homogenizing volume'. It is unclear why one would want to combine a number of specimens less than N , or any number of specimens to simultaneously analyze the mixture only to deconvolute the results."

The question here is whether the disclosure is enabling. As long as those skilled in the art can practice the claimed process steps without undue experimentation, the disclosure is enabling. The "reasoning" or "why" for a given step is immaterial to the enablement of the step. However, applicant has set forth the "reasoning" and the "why" as explained under the heading "Background of the Invention". The reasoning for introducing a combination of specimens and then deconvoluting the results is to reduce the signal-to-noise ratio in the results in a shorter period of time. From this follows a higher throughput when analyzing a large number of samples.

The examiner states: "It is unclear how combining the specimens would be an advantage over the prior art when it has already been disclosed the individual specimens may

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be analyzed simultaneously.” Again, the issue here is enablement. The advantages over the prior art are unrelated to whether the disclosure enables those skilled in the art to practice the invention without undue experimentation. However, as already explained, the combining of specimens as set forth in applicant’s claims enables the reduction of the signal-to-noise ratio in the analysis of numerous samples in a shorter period of time. Moreover, the prior art does not disclose “individual specimens may be analyzed simultaneously” using the same instrument. Norman U.S. Patent No. 5,508,204 discloses sequential, not simultaneous analysis. If all samples (specimens) were mixed and fed to an analytical instrument simultaneously, no sample could be analyzed. The advantage of submitting combinations less than all of the samples is to enable deconvolution and thus obtain spectra of all samples with reduced signal-to-noise ratios.

The examiner states: “There is also lack of basis of what is meant by ‘homogenizing’ and the importance of being this step. The examiner considers an individual specimen, which contains different elements to be homogenized, and furthermore any mixture is a combination of uniformly distributed substances.”

* The examiner may consider that a mixture is a combination of uniformly distributed substances, but in fact, when fluid specimens are first combined, they are not uniformly distributed and, therefore, the applicant includes the step of introducing the combination of specimens “into a homogenizing volume to create a homogenized specimen.” The specimens become uniformly distributed in the homogenizing volume prior to being introduced into the analytical instrument.

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The examiner states: "The specification also fails to particularly show a working example in which a programmable digital computer is employed to mathematically process the recorded data."

The specification at page 5, line 21 - page 6, line 2, describes the mathematical basis of deconvolution. Programs for performing deconvolution are known to those of ordinary skill in the art. As stated in applicant's specification, the Hadamard transform method is well known in spectroscopy and is essentially based on solving simultaneous equations in unknowns to deconvolute the stored results. Disclosures are addressed to those of ordinary skill in the art. As stated in MPEP §2164: "Detailed procedures for making and using the invention may not be necessary if the description of the invention itself is sufficient to permit those skilled in the art to make and use the invention." As stated in MPEP §2164.01: "A patent need not teach, and preferably omits, what is well known in the art."

The examiner states:

The disclosure also lacks the proper evidence to determine that the method could be performed as claimed to allow one to obtain the results as claimed by applicant. The method suggests that two or more unknown samples are mixed together and then are subjected to analysis that allows one to identify characteristics of the individual samples. However, it is well known in the art that when chemicals are mixed together, chemical reactions may occur in which a new chemical is produced or the original samples are altered or entirely consumed in the reaction. Since the originally prepared samples may be altered or consumed, it is unclear how one would analyze the mixed samples and then deconvolute the results to obtain data that would identify or relate to the original samples. This would be particularly difficult or incorrect if the original samples are consumed in

the reaction. Since the mixing of the samples may provide for the occurrence of unpredictable chemical reactions, it is unclear how such a method could be accurately executed as claimed by applicant. Therefore, the scope of the disclosure does not provide adequate support for enablement of the objective of the invention which appears to be in contrast of generally accepted scientific principles of mixing and analyzing chemicals.

The examiner is asserting that the invention is "in contrast of generally accepted scientific principles of mixing and analyzing chemicals." However, it is well known that most chemicals do not react with each other instantaneously or at all and, therefore, even based upon known scientific principles, applicant's claimed invention satisfies the requirements of 35 U.S.C. § 112 in describing a useful method. Moreover, filed herewith is a Declaration Under 37 C.F.R. § 132 of the inventor setting forth the results of two experiments, one in which three chemical compounds were analyzed two at a time and then resolved into individual spectra, and another example in which seven chemicals were analyzed four at a time and then resolved into individual spectra. The Declaration establishes that applicant's method is not contrary to scientific principles. Simply stated, applicant's method is useful in all situations where those of ordinary skill in the art might chose to apply it. It would not involve undue experimentation to avoid combinations of chemicals that instantly react.

The examiner states "Claim 2 recites that the specimens are gaseous specimens diluted with a carrier gas. The only mentioning of gas is found in the Background of the Invention on page 1, line 11 and Summary of the Invention on page 2, lines 27-28. However, there is no working example given with which the specific method would be employed."

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As pointed out above, a specific working example is not required to satisfy the enablement requirement of 35 U.S.C. § 112, first paragraph, so long as those skilled in the art can practice the invention claimed without undue experimentation. There is no reason to believe that gaseous specimens would be more difficult to use than other fluid specimens.

The examiner states:

As recited above the prior art discloses the well known method of performing simultaneous mass spectroscopy analysis of samples, which may be injected into a system by means of electrospray nozzles (as given prior art, see Background of the Invention, page 1, lines 6-10) that may be deconvoluted by means of the Hadamard transform and it is well known that a computer may be employed to perform this mathematical method. It appears that applicant has taken well-known methods and principles (as admitted by applicant) to produce a method in which applicant now recites that multiple samples are combined. However, due to the lack of working examples and evidence of how such a method would be beneficial the examiner hereby asserts that the specification is not enabled for the claimed method.

Again, the rejection here is enablement under 35 U.S.C. § 112, first paragraph. Whether an invention is beneficial (useful) or whether the invention is enabled are two different questions. As set forth above, the reason the invention is beneficial is that the signal-to-noise ratio of the obtained spectra can be reduced in a shorter period of time. A working example is not required to demonstrate this fact. Moreover, the § 132 Declaration submitted herewith clearly establishes that the invention is useful.

The examiner's acknowledgement that the applicant has used well-known methods and principles in the implementation of his methods (which have already been established to be new and nonobvious satisfying the provisions of 35 U.S.C. §§ 102 and 103), is, in fact, an acknowledgment that those of ordinary skill in the art can practice the claimed

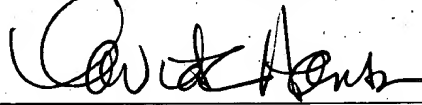
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method without undue experimentation and, therefore, the enablement requirement of 35 U.S.C. § 112, first paragraph, is satisfied by the applicant's specification.

In view of the foregoing remarks and the § 132 Declaration submitted herewith, it is respectfully submitted this application is now in condition for allowance.

Respectfully submitted,

WEBB ZIESENHEIM LOGSDON
ORKIN & HANSON, P.C.

By 

David C. Hanson, Reg. No. 23,024
Attorney for Applicant
700 Koppers Building
436 Seventh Avenue
Pittsburgh, PA 15219-1818
Telephone: (412) 471-8815
Facsimile: (412) 471-4094
E-mail: webblaw@webblaw.com